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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 09/770,562 | 01/26/2001 | William J. Curatolo | 8191-87018-01 | 8513 |
| 24197 7590 12/22/2011 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204 | | | EXAMINER FUBARA, BLESSING M | |
| | | | ART UNIT 1613 | PAPER NUMBER |
| | | | NOTIFICATION DATE 12/22/2011 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|---|--------------------------------------|--|
| Advisory Action Before the Filing of an Appeal Brief | Application No. 09/770,562 | Applicant(s) CURATOLO ET AL. |
| | Examiner BLESSING FUBARA | Art Unit 1613 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 November 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1,4,23,36,37,49-51,53-56 and 58.
 Claim(s) withdrawn from consideration: 28-35,38 and 57.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/Blessing M. Fubara/
 Primary Examiner, Art Unit 1613

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's argument that none of the cited references disclose completely amorphous drug molecularly dispersed is not persuasive because the claims do not say anything about completely amorphous and spray drying produces solid amorphous dispersion since claim 1 claims spray dried solid amorphous dispersion and there is nowhere in applicant's specification that says that spray drying produces completely amorphous dispersion. However, if spray drying in applicant's specification leads to completely amorphous dispersion, then the spray drying in the prior art would also lead to completely amorphous dispersion. It is not improper to say that if applicant's spray drying leads to completely amorphous solid dispersion, then spray dried compositions of the prior art should also be completely amorphous. While applicant insists that certain spray drying conditions are necessary to produce completely amorphous solid dispersions, the claims have not recited those conditions that are necessary for completely amorphous dispersions and the claims have not recited completely amorphous. Spray drying is a known pharmaceutical process and the prior art does not have to describe what is already well in the art and a process that is well known and has been tested is enabled. Therefore, Miyajima, Kigoshi and Hikosaka are enabled with regards to spray drying because spray drying is a well-known process in the art. Applicant's arguments, all have to do with enablement of the references cited. However, Applicant has failed to factually show that the drug is not amorphous. Applicant's solid amorphous dispersion is obtained by spray drying and there is no disclosure of the conditions applicant may be referring to that must be present in order for the drug to be amorphous. Applicant has not provided a list of solvents and the conditions that are necessary for a drug dissolved in that solvent together with HPMCAS that when spray dried would lead to amorphous drug and these are not in the claims. Applicant has not provided factual evidence that the drugs in the spray dried products of Miyajima, Kigoshi and HIKOSAKA are not amorphous.

Declaration: The impressive qualification of Ann W. Newman and Ronald Bayerick has been acknowledged by the examiner. However, the declaration under 37 CFR 1.132 filed 11/28/2011 is insufficient to overcome the rejection of the pending claims based upon the prior art of record and as set forth in the last Office action because: spray drying is a known technique and what is well known in the art does not have to be taught in the art--- A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). No specific conditions and parameters have been named and claimed that would produce or not produce completely amorphous product; the parameters the declarant is naming are not in the claims; the declaration has not factually shown that the spray drying technique that is well known in the art is not enabled.